

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

WENDY CANADY, etc.,

Plaintiff,

Case No. 3:11 oe 40011

-vs-

MEMORANDUM OPINION

ORTHO-MCNEIL PHARMACEUTICAL, INC.,
et al.,

Defendant.

KATZ, J.

I. Introduction

Plaintiff Wendy Canady, an Oregon resident, brought this action on behalf of her daughter Ashley Rachunok (collectively “Plaintiffs”) against Defendants Ortho-McNeil Pharmaceutical, Inc., Alza Corporation, Johnson & Johnson Pharmaceutical Research & Development, LLC, and Johnson & Johnson (collectively “Defendants”). Ms. Rachunok, a minor at the time of her alleged injury, as well as the time this suit was filed, alleges she had been prescribed the Ortho Evra® birth control patch which caused her to have a pulmonary embolism. (Doc. No. 1).

Prior to this action, the Court granted Defendants’ motion for summary judgment on Plaintiffs’ failure to warn claim sounding in negligence but denied summary judgment on Plaintiffs’ strict liability failure to warn claim. *Canady v. Ortho McNeil Pharm., Inc., et al.*, No. 11-oe-40011, 2014 U.S. Dist. LEXIS 57316 (N.D. Ohio Apr. 24, 2014). The Court also denied Defendants’ motion for judgment on the pleadings for the remaining causes of action under Oregon law. *Id.*

Defendants now move for summary judgment on Plaintiffs’ claims of strict liability failure to warn, negligence, breach of express and implies warranties, and fraud. (Doc. Nos. 16, 17).

Plaintiffs filed responses (Doc. Nos. 19, 21) and Defendants replied (Doc. Nos. 22, 23). On September 23, 2014, the Court heard oral argument on the pending motions for summary judgment in this case and several other cases concerning the Ortho Evra® birth control patch. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332.

II. Facts

Ms. Rachunok was first prescribed the Ortho Evra® birth control patch on November 11, 2009 by Hallie Goffrier, PA at the Salem Pediatric Clinic in Oregon. Goffrier is an Oregon-licensed physician assistant and has specialized in children and adolescent medicine at the Clinic since May 2008. Ms. Rachunok filled the Ortho Evra® prescription twice in November 2009; and twice received the January 2008 FDA approved package insert and detailed patient labeling. There is no dispute the Ortho Evra® patch was approved by the FDA. *Yates v. Ortho-McNeil Pharm., Inc.*, No. 1:09-oe-40023, 2014 U.S. Dist. LEXIS 47722, at *7 (N.D. Ohio Apr. 7, 2014). Further, the FDA also approved the product's package insert which warned of the increased risks of blood clots and pulmonary embolism.

The record reflects Goffrier was aware Ortho Evra® may increase the risk of blood clots and pulmonary embolism; and that Goffrier felt the benefits outweighed the risks when she prescribed the Ortho Evra® patch to Ms. Rachunok. Moreover, the January 2008 FDA approved Ortho Evra® package insert was in effect at the time Goffrier prescribed the Ortho Evra® birth control patch.

Before Goffrier prescribed the Ortho Evra® patch, neither Ms. Rachunok nor her mother saw any advertisements, read anything, or performed any research about Ortho Evra®. Ms. Rachunok and her mother testified they relied exclusively upon Goffrier's judgment in deciding to

use Ortho Evra®. They also testified they had never heard of Ortho Evra® until it was recommended by Goffrier. Plaintiffs concede they did not read the information on the Ortho Evra® boxes, packaging materials, package insert, or detailed patient labeling.

III. Summary Judgment

Summary judgment is proper where “there is no genuine dispute as to any material fact” and the moving party “is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A party asserting a genuine issue of material fact must support the argument either by “citing to particular parts of materials in the record” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1). The Court views the facts in the record and reasonable inferences that can be drawn from those facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The Court does not weigh the evidence or determines the truth of any matter in dispute. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

The party requesting summary judgment bears an initial burden of demonstrating that no genuine issue of material fact exists, which the party must discharge by producing evidence to demonstrate the absence of a genuine issue of material fact or “by showing . . . that there is an absence of evidence to support the nonmoving party’s case.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986) (internal quotation marks omitted). If the moving party satisfies this burden, the nonmoving party “may not rest upon its . . . pleadings, but rather must set forth specific facts showing that there is a genuine issue for trial.” *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009) (citing Rule 56 and *Matsushita*, 475 U.S. at 586). The party opposing the summary

judgment motion must present sufficient probative evidence supporting its claim that disputes over material facts remain; evidence that is “merely colorable” or “not significantly probative” is insufficient. *Anderson*, 477 U.S. at 248–52.

IV. Discussion

Oregon law defines a product liability action as a “civil action brought against a manufacturer, distributor, seller or lessor of a product for damages arising out of: (1) any design, inspection, testing, manufacturing or other defect in a product; (2) any failure to warn regarding a product; (3) any failure to properly instruct in the use of a product.” Or. Rev. Stat. § 30.900. This statute “embraces all theories a plaintiff can claim in an action based on a product defect.” *Kambury v. DaimlerChrysler Corp.*, 60 P.3d 1103, 1105 (Or. Ct. App. 2003). This includes claims for negligence, strict liability, breach of warranty, and fraudulent misrepresentation. *Simonson v. Ford Motor, Co.*, 102 P.3d 710, 714–15 (Or. Ct. App. 2004).

A. Failure to Warn

For a strict liability claim against a manufacturer for personal injury arising out of failure to warn, a plaintiff must show the product was in a defective condition unreasonably dangerous. *Crosswhite v. Jumpking, Inc.*, 411 F. Supp.2d 1228, 1231 (D. Or. 2006); *see also* Or. Rev. Stat. § 30.900(2). In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning. *Crosswhite*, 411 F. Supp.2d at 1233. However, where warning is given, the seller may reasonably assume that warning was read and heeded; and a product bearing such a warning is not in a defective condition, nor is it unreasonably dangerous. *Id.* (quoting *Benjamin v. Wal-mart Stores, Inc.*, 61 P.3d 257, 264 (Or. Ct. App. 2003)).

In addition to establishing proof that a product was in a defective condition unreasonably dangerous, a plaintiff must establish the alleged inadequate warning proximately caused her injuries or damage. *Crosswhite*, 411 F. Supp.2d at 1235) (citing *Gilmour v. Norris Paint & Varnish Co., Inc.*, 627 P.2d 1288 (Or. Ct. App. 1981)). Specifically, a plaintiff must demonstrate the lack of different or additional warnings caused her injuries. *Crosswhite*, 411 F. Supp.2d at 1235. Causation cannot be established when a plaintiff failed to read or ignored the alleged inadequate warning that specifically cautioned the precise risk at issue. *Id.*; see also *Bartlett v. MacRae*, 635 P.2d 666, 667-68 (Or. Ct. App. 1981).

Defendants argue Plaintiffs have failed to show proximate cause. Plaintiffs do not oppose to this argument and instead counter their failure to warn claim is not barred by the learned intermediary doctrine. However, Plaintiffs' argument is moot because the Court, in a prior memorandum opinion, already agreed the learned intermediary doctrine did not apply to this claim.

As Defendants point out, there is no evidence the alleged inadequate warning was the proximate cause of Ms. Rachunok's injury. The record is clear Plaintiffs failed to read the detailed patient labeling, which explicitly warned of the precise injury that resulted. See *Bartlett*, 635 P.2d at 667-68. Moreover, Goffrier knew of the risks associated with Ortho Evra®, yet felt the benefits outweighed the risk and prescribed the medication to Ms. Rachunok. Given Plaintiffs' testimony that they relied exclusively on Goffrier's medical judgment, Plaintiffs' have not shown they would have deviated from their decision to follow Goffrier's advice and recommendation given an additional warning. Accordingly, the Court finds Plaintiffs have not

established the necessary causation element for a strict liability failure to warn claim under Oregon law.

B. Design and Manufacturing Defect

Plaintiffs assert Defendants are negligent because they “breached their duty of reasonable care . . . in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold the subject product.” (Master Complaint, Doc. No. 18-6, Ex. D, ¶ 89). Accordingly, Plaintiffs negligence claims are properly construed as product liability claims governed by Oregon Revised Statute § 30.900. *See Kambury*, 60 P.3d 1103 at 1105; *Simonson* 102 P.3d at 714–15. (Or. Rev. Stat. § 30.900 embraces all theories a plaintiff can claim in an action based on a product defect, including claims of negligence).

Oregon law provides a product manufacturer is liable for harms caused by products which are “in a defective condition unreasonably dangerous to the user.” Or. Rev. Stat. § 30.920(1). Oregon has adopted the “consumer expectations test” for manufacturing or design defect. *Crosswhite*, 411 F. Supp.2d at 1231. Under this test, the plaintiff must prove that when the product left the defendants hands, the product was: (1) in a defective condition not contemplated by the ultimate consumer which made it unreasonably dangerous; and (2) the defective product was dangerous to an extent beyond that which the ordinary consumer would have expected.” *Id.*; Or. Rev. Stat. § 30.920. A plaintiff bears the burden of proof that the product was defective; and unless evidence is produced which will support the conclusion that it was defective, the burden is not sustained. *Crosswhite*, 411 F. Supp.2d at 1231; (quoting § 402A of the Restatement (Second) of Torts)).

Here, Plaintiffs have not submitted any evidence to meet this burden. Plaintiffs have merely relied on their bare allegation that there was a design defect without putting forth any evidence Ortho Evra®'s FDA-approved design was dangerous to an extent beyond that which the ordinary consumer would have expected. The record is clear the detailed patient labeling warned of the precise injury at issue. It is also undisputed that Plaintiffs healthcare provider prescribed the Ortho Evra® birth control patch to Ms. Rachinok knowing the risks associated therewith.

Plaintiffs have also failed to offer a practicable alternative design of the FDA approved Ortho Evra® birth control patch that would have eliminated the unsafe characteristics without destroying its utility. *McCathern v. Toyota Motor Corp.*, 23 P.3d 320 (2001) (consumer expectations may exceed a jury's common experience, and the plaintiff may need to produce evidence relevant to risk-utility analysis showing that a safer alternative design for the product exists). Absent the required proof, these claims fail as a matter of law.

C. Breach of Express and Implied Warranty

Under Oregon law, a breach of express warranty claim requires a plaintiff to prove defendants made: (1) an affirmation of fact or promise made to the plaintiff; (2) relating to the goods; (3) which becomes part of the basis of the bargain; and (4) affirming that the goods will conform to the affirmation or promise. *Jorritsma v. Farmers' Feed & Supply Co., Inc.*, 538 P.2d 61, n. 3 (Or. App. Ct. 1975).

To state a claim for breach of implied warranty of merchantability under Oregon law, a plaintiff must establish: (1) the sale of goods; (2) that the seller of the goods is a merchant with respect to those goods; (3) that the goods were not of merchantable quality, i.e., that the goods are not fit for the ordinary purposes for which such goods are used. Or. Rev. Stat. § 72.3140; *Allen v.*

G.D. Searle & Co., 708 F. Supp. 1142, 1159 (D. Or. 1989). A warranty of fitness for a particular purpose arises regardless of the seller's intent whenever (a) the buyer relies on the seller's skill and judgment to select or furnish suitable goods, and (b) the seller at the time of contracting has reason to know the buyer's purpose and that the buyer is relying on the seller's skill and judgment. *Controltek, Inc. v. Kwikie Enterprises, Inc.* 585 P.2d 670, 673 (Or. 1978).

Oregon Revised Statute § 72.6070(3)(a) provides when a tender of goods has been accepted, "[t]he buyer must within a reasonable time after the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." *See also Parkinson v. Novartis Pharms. Corp.*, No. 12-cv-2089, 2014 U.S. Dist. LEXIS 36677, *26 (D. Or. March 20, 2014). Oregon courts have held "notice is an essential element of plaintiff's case" for breach of warranty. *Redfield v. Mead, Johnson & Co.*, 512 P.2d 776, 781 (Or. 1973); *see also Parkinson*, 2014 U.S. Dist. LEXIS 36677, at *26 (commencement of lawsuit does not constitute notice under Or. Rev. Stat. § 72.6070).

Defendants move for summary judgment on Plaintiff's breach of warranty claims based on Plaintiffs failure to give the required notice under Oregon law. Plaintiffs fail to address the notice requirement and maintain their breach claims should not be dismissed because they relied on Defendants false warranties.

In the absence of any authority abolishing the notice requirement, and in the absence of any evidence that Plaintiffs gave Defendants notice, the Court finds Plaintiffs have failed to establish an essential element of their claims. *Parkinson*, 2014 U.S. Dist. LEXIS 36677, at *29-30 (quoting *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1160 (D. Or. 1989)). In addition, Plaintiffs have also failed to establish reliance, or that the Ortho Evra® birth control patch was not

fit for a particular purpose. It is undisputed Ms Rachunok used the Ortho Evra® birth control patch for its intended purpose as a hormonal birth control. It is also undisputed Plaintiffs never read the detailed patient labeling which warned Plaintiffs of very risks at issue. Accordingly, Plaintiffs causes of action for breach of express and implied warranties fail as a matter of law.

D. Negligent Misrepresentation, Fraud and Deceit, Fraudulent Misrepresentation, and Fraudulent Concealment

To maintain a fraud based claim under Oregon law, a plaintiff must show, among other elements, reliance on a false representation. *Allen*, 708 F. Supp. at 1160 (citing *Rice v. McAllister*, 519 P.2d 1263, 1265 (Or. 1974)). Here, Plaintiff never read the detailed patient labeling, saw any advertisements, or read anything about the Ortho Evra® birth control patch prior to Goffrier prescribing it. There is no dispute Plaintiffs relied exclusively on Goffrier for information about the Ortho Evra® birth control patch. Because there is no evidence Plaintiffs relied on any alleged false representation made by Defendants, Plaintiffs' fraud based claims are dismissed as a matter of law.

V. CONCLUSION

Accordingly, the Defendants' motions for summary judgment (Doc Nos. 16, 17) are granted and Plaintiffs' claims are dismissed.

IT IS SO ORDERED.

s/ David A. Katz
DAVID A. KATZ
U. S. DISTRICT JUDGE